MEDICAL EVALUATORS
OF TEXAS ASO, L.L.C.
2211 West 34th St. ● Houston, TX 77018
800-845-8982 FAX: 713-583-5943

DATE OF REVIEW: **June 30, 2016**

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Denial of request for left C7-T1 epidural steroid injection with fluoroscopy under sedation CPT codes; 62310, 77003, 01992.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
This case was reviewed by a physician who holds a board certification in Anesthesiology with sub-certification in Pain Medicine and is currently licensed and practicing in the state of Texas.

REVIEW OUTCOME
Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld

CLINICAL HISTORY [SUMMARY]:
The claimant is a male who was injured neck and lower back on XX/XX/XX while he was trying to lift a large container. The claimant has been previously treating with physical therapy, epidural steroid injection and medications including Tramadol, Cyclobenzaprine, Tizanidine and Lyrica. The claimant had C6-C7 fusion on XX/XX/XX. CT scan of the cervical spine dated XX/XX/XX revealed posterior osteophyte formation at the C6-7 level with mild canal stenosis and mild to moderate bilateral neural foraminal narrowing, left worse than right, status post ACDF C6-7, and no abnormal fluid collection or other postsurgical complication identified.

Office visit dated X/XX/XX indicates that the claimant did not even get temporary pain relief from a selectve nerve root block through epidural catheter done on X/XX/XX. The claimant continues to have significant pain. The claimant complained of posterior cervical region pain traveling down the left shoulder into the left forearm and hand with sharp pain in all fingers and allodynia in forearm. The claimant first noticed immediately following his cervical spine surgery done on XX/XX/XX. The claimant had EMG/NCV on XX/XX/XX that revealed left C7 and T1 radiculopathies. XX is requesting a left C6-7 selective nerve root block. The claimant complained of 8/10 pain located in the neck and low back with tingling, numbness, burning sensation, stabbing, tender and radiating. The severity of pain was 7 to 9, and present all the time and relieved by medciations. The physical examination showed decreased cervical spine rotation to the left and the right. Decreased cervical spine extension and flexion. On exam of extremities, left hand was significantly cooler than the right hand and left hand and forearm was darker thant the right hand. The 5th finger was contracted with the PIP joint abnormally extended outwards. The left hand

grip strength was significantly decreased. Flexion of the left forearm was weak and left shoulder elevation was decreased. There was multiple posterior cervical spine tender points. Neurological examination revealed unable to perform a triceps reflex on the left arm due to hyperalgesia, right triceps reflex was 2/4, right patella reflex was 2/4, left patella reflex was 3/4, and Hoffman's reflex was negative bilaterally. There was left C6 and C7 hypoesthesia and left C7, 8 and T1 hyperesthesia and allodynia. The assessment was postlaminectomy syndrome; spinal stenosis, cervical region; radiculopathy, cervical region; complex regional pain syndrome I of left upper limb; and other hereditary and idiopathic neuropathies. XX recommended left C7-T1 block as he did not get significant relief following the X/XXXX left C6-7 block.

Progress note dated XX/XX/XX indicates the claimant complained of left arm pain and weakness are unchanged. He reported that his left arm is numb and indicated that the most recent request for a second cervical ESI was denied. Objective findings include severe weakness in the left upper extremity, which was unchanged from the his last exam. XX recommended selective nerve root injections at C6-7 and C7-T1 on the left side both as a diagnostic as well as a therapeutic intervention.

Prior UR dated X/XX/XX denied the request for left C7-T1 epidural steroid injection with fluoroscopy under sedation CPT codes; 62310, 77003, 01992 because it was not recommended as medically necessary. It was noted that "The initial request was noncertified noting that the documentation submitted for review indicated the patient continued to have complaints of pain in the cervical region. The patient underwent a previous left C6-7 selective nerve root block on X/XX/XX which did not help. Although a magnetic resonance imaging (MRI) of the cervical spine was mentioned, the official report was not provided for review with positive findings of impingement that correlates with physical exam findings at the requested levels. Also, the documentation failed to provide findings of severe anxiety to warrant the need for sedation. There is insufficient information to support a change in determination and the previous non-certification is upheld. The Official Disability Guidelines note that cervical epidural steroid injections are not recommended based on recent evidence, given the serious rikss of this procedure in the cervical region, and the lack of quality evidence for sustained benefit. There is no documentation of extreme anxiety or needle phobia to support sedation. Therefore, medical necessity Is not established in accordance with current evidence based guidelines."

ANALYSIS AND EXPLANATION OF THE DECISION:

After review of the records submitted, the previous adverse determination for the request of left C7-T1 epidural steroid injection with fluoroscopy under sedation is upheld. This claimant continues to have neck and left arm pain. The claimant had first ESI on X/XX/XX at left C6-C7, which did not receive any pain relief from this injection. According to Official Disability Guidelines (ODG), cervical epidural steroid injections are not recommended based on recent evidence, given the serious risks of this procedure in the cervical region, and the lack of quality evidence for sustained benefit. Additionally, the requested

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procedure is under sedation, but there is no documentation that the claimant has severe anxiety or needle phobia to support sedation. Furthermore, the only diagnostic study provided was CT scan of the cervical spine dated XX/XX/XX that showed no pathology or inconclusive pathology at the proposed level at C7-T1.

Therefore, based on the Official Disability Guidelines (ODG) and the clinical documentation stated above, the request for left C7-T1 epidural steroid injection with fluoroscopy under sedation CPT codes; 62310, 77003, 01992 is not medically necessary.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

X **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES – Online Version**
Neck and Upper Back (Acute & Chronic) - Accessed XX/XX/XX
Epidural steroid injection (ESI)
Not recommended based on recent evidence, given the serious risks of this procedure in the cervical region, and the lack of quality evidence for sustained benefit. These had been recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy), with specific criteria for use below. In a previous Cochrane review, there was only one study that reported improvement in pain and function at four weeks and also one year in individuals with radiating chronic neck pain. (Peloso-Cochrane, 2006) (Peloso, 2005) Other reviews have reported moderate short-term and long-term evidence of success in managing cervical radiculopathy with interlaminar ESIs. (Stav, 1993) (Castagnera, 1994) Some have also reported moderate evidence of management of cervical nerve root pain using a transforaminal approach. (Bush, 1996) (Cyteval, 2004) A previous retrospective review of interlaminar cervical ESIs found that approximately two-thirds of patients with symptomatic cervical radiculopathy from disc herniation were able to avoid surgery for up to 1 year with treatment. Success rate was improved with earlier injection (< 100 days from diagnosis). (Lin, 2006) There have been case reports of cerebellar infarct and brainstem herniation as well as spinal cord infarction after cervical transforaminal injection. (Beckman, 2006) (Ludwig, 2005) Quadriparesis with a cervical ESI at C6-7 has also been noted (Bose, 2005) and the American Society of Anesthesiologists Closed Claims Project database revealed 9 deaths or cases of brain injury after cervical ESI (1970-1999). (Fitzgibbon, 2004) These reports were in contrast to a retrospective review of 1,036 injections that showed that there were no catastrophic complications with the procedure. (Ma, 2005) The American Academy of Neurology concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) In other studies, there was evidence for short-term symptomatic improvement of radicular symptoms with epidural or selective root injections with corticosteroids, but these treatments did not appear to

decrease the rate of open surgery. (Haldeman, 2008) (Benyamin, 2009) Some have said epidural steroid injections should be reserved for those who may otherwise undergo open surgery for nerve root compromise. (Bigos, 1999) There is limited evidence of effectiveness of epidural injection of methyl prednisolone and lidocaine for chronic MND with radicular findings. (Peloso-Cochrane, 2006) The FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. (FDA, 2014)

Recent evidence: ESIs should not be recommended in the cervical region, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee concluded. Injecting a particulate steroid in the cervical region, especially using the transforaminal approach, increases the risk for sometimes serious and irreversible neurological adverse events, including stroke, paraplegia, spinal cord infarction, and even death. The FDA has never approved an injectable corticosteroid product administered via epidural injection, so this use, although common, is considered off-label. Injections into the cervical region, as opposed to the lumbar area, are relatively risky, and the risk for accidental injury in the arterial system is greater in this location. (FDA, 2015) An AMA review suggested that ESIs are not recommended higher than the C6-7 level; no cervical interlaminar ESI should be undertaken at any segmental level without preprocedural review; & particulate steroids should not be used in therapeutic cervical transforaminal injections. (Benzon, 2015) According to the American Academy of Neurology (AAN), ESIs do not improve function, lessen need for surgery, or provide long-term pain relief, and the routine use of ESIs is not recommended. They further said that there is in particular a paucity of evidence for the use of ESIs to treat radicular cervical pain. (AAN, 2015) In this comparative-effectiveness study, no significant differences were found between ESI and conservative treatments. (Cohen, 2014) See the Low Back Chapter, where ESIs are recommended as a possible option for short-term treatment of radicular pain in conjunction with active rehab efforts, but they are not recommended for spinal stenosis or for nonspecific low back pain.

While not recommended, cervical ESIs may be supported using Appendix D, Documenting Exceptions to the Guidelines, in which case:
Criteria for the use of Epidural steroid injections, therapeutic:
Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.
(1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing.
(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
(3) Injections should be performed using fluoroscopy (live x-ray) for guidance
(4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections.
(5) No more than two nerve root levels should be injected using transforaminal blocks.

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(6) No more than one interlaminar level should be injected at one session.
(7) In the therapeutic phase, repeat blocks should only be offered if there is at least 50% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year.
(8) Repeat injections should be based on continued objective documented pain and function response.
(9) Current research does not support a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.
(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or stellate ganglion blocks or sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.
(11) Cervical and lumbar epidural steroid injection should not be performed on the same day;
(12) Additional criteria based on evidence of risk:
(a) ESIs are not recommended higher than the C6-7 level;
(b) Cervical interlaminar ESI is not recommended; &
(c) Particulate steroids should not be used. (Benzon, 2015)

Criteria for the use of Epidural steroid injections, diagnostic:
To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below:
(1) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies;
(2) To help to determine pain generators when there is evidence of multi-level nerve root compression;
(3) To help to determine pain generators when clinical findings are suggestive of radiculopathy (e.g. dermatomal distribution), and imaging studies have suggestive cause for symptoms but are inconclusive;
(4) To help to identify the origin of pain in patients who have had previous spinal surgery.

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